

Pharma Dosage Forms

Premium Quality

Audit Date	Agency	Type of Inspiration	Audit Status
Oct-09	EMEA	Regulatory	No critical observations.
Aug-09	FDA (CDER)	Regulatory	No 483.
Jun-09	EMEA	Regulatory	No critical observations.
Apr-09	TGA – Australia	Regulatory	No critical observations.
Nov-08	MoH - Mexico	Regulatory	No report issued to DPI. No observations.
Jan-08	EMEA	PAI / Regulatory	One critical observation. Responses accepted; product approved.
Nov-07	Korean FDA	Regulatory	No report issued to DPI. No critical observations.
Sep-07	DEA	Regulatory	No observations.
Aug-07	EMEA	Regulatory	No critical observations.
Jul-07	MoH – Mexico	Regulatory	No report issued to DPI. No critical observations.
Jun-07	LGASH	Regulatory	No critical observations.
Jan-07	FDA (CDER)	PAI / General	No 483.
Jan-07	Brazilian Health Authority (ANVISA)	Regulatory	No report issued to DPI.

DSM's quality systems are driven by a suite of validated computerized systems. SAP manages material control, release, preventative maintenance, and calibration. Documentum is used for document and work order control, while LIMS manages lab data. Trackwise manages deviation, change control, audit findings and corrective actions.

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DSM uses a proprietary software system called iMost for planning, scheduling, and as a data hub. This is also used to provide online real-time batch data to clients. These systems are fully integrated, and provide consistent and timely reporting to ensure up-to-date availability of all relevant supply chain data, including batch release status.

The Greenville facility is approved by the FDA, EMEA and many other international regulatory agencies, enabling DSM to ship to countries throughout the world. The infrastructure and unstinting approach to quality, which includes predictive modeling and risk analysis, represents invaluable service to customers.

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Regulatory Excellence

DSM's track record and reputation among regulatory bodies is exemplary. We implement a regulatory strategy based on in-depth knowledge of FDA procedures and guidelines. More than 90% of pre-approval inspections (PAIs) have been waived over the last three years, which reflects a major benefit to customers in terms of optimizing time to market. Greenville is also a DEA-licensed facility, and mandated DEA processes are supported by state-of-the-art security, planning and scheduling.

This level of performance and reputation is not only appealing to companies with new business to place, but also to those with existing products at outdated or unsuitable facilities. Tech transfer to the Greenville site can be achieved quickly and cost-effectively, with long-term cost benefits for commercial product supply.

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